

**510(k) Summary of Safety and Effectiveness
Jet-X® Half Pins**

Submitted By:

Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

FEB 05 2003

Date:

November 22, 2002

Contact Person:

David Henley
Senior Clinical/Regulatory Affairs Specialist
Tel: (901) 399-6487
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Proprietary Name:

Jet-X Half Pins

Common Name:

Half Pins

Classification Name and Reference:

Smooth or threaded metallic bone fixation fastener,
21CFR888.3040, Class II

Device Product Code and Panel Code:

JDW/Orthopedics/87

Device Description:

The Jet-X Half Pin is a modification of the Jet-X TiN Coated Half Pin that was cleared for market under K023134. This submission describes design modifications to the threads and provides for a hydroxylapatite (HA) coated stainless steel half pin.

Intended Use:

The Jet-X Half Pin is intended to be used with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or nonunion of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

Technological Characteristics:

The principles of operation for the Jet-X Half Pin are identical to the Jet-X TiN Coated Half Pin. Both are half pins that are used with external fixation systems for fracture fixation (open and closed) and other indications listed above. The hydroxylapatite (HA) coating is the same coating currently used on Smith & Nephew's HA Global Taper Tapered (Synergy) Hip Stems (K970337). The Orthofix External Fixation Screw (K974186) marketed by Orthofix SRL also has a HA coating applied to the threaded area. The design and material of the Jet-X Half Pin has the same technological characteristics as one or more of the predicate devices.

Substantial Equivalence Information:

The intended use of the Jet-X Half Pin is identical to the Jet-X TiN Coated Half Pin. The Jet-X Half Pin shape and design are also very similar to the Jet-X TiN Coated Half Pin. The subject device is manufactured from the identical 316L stainless steel material as is used to manufacture the Jet-X TiN Coated Half Pin. The HA coating is identical to the coating used on Smith & Nephew's HA Global Taper Tapered (Synergy) Hip Stems (K970337). It is similar to the HA coating used on the Orthofix External Fixation Screw (K974186) marketed by Orthofix SRL.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 05 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K023921

Trade/Device Name: Jet-X® HA Coated Half Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW
Dated: January 15, 2003
Received: January 16, 2003

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

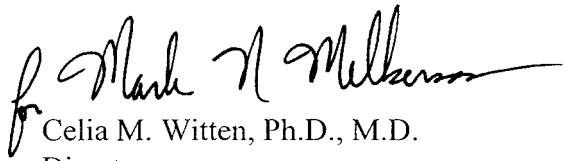
Page 2 – Mr. David Henley

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use Statement
Jet-X® HA Coated Half Pin**

510(k) Number (if known): _____

Device Name: **Jet-X® HA Coated Half Pin**

Indications for Use:

The Jet-X HA Coated Half Pin is intended to be used with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or nonunion of long bones; limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Wilkerson
Division Sign-Off
Division of General, Restorative
and Neurologic Devices

510(k) Number: *K023921*

Prescription Use *h*
(Per 21 CFR 801.109)

OR

Over-The Counter Use *h*
(Optional Format 1-2-96)